PC7068AADO

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE:	**U.S. Patent No. 4,959,366**	:
ISSUED:	**September 25, 1990**	:
TO:	**Peter E. Cross, et al.**	:
FOR:	**Anti-Arrhythmic Agents**	:
FROM:	**Serial No. 44,086**	:
FILED:	**April 29, 1987**	:

Box Patent Extension
Assistant Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL LETTER FOR
APPLICATION FOR EXTENSION OF
PATENT TERM UNDER 35 U.S.C 156

Sir:

Transmitted herewith is the application of PFIZER INC. for extension of the term of United States Patent No. 4,959,366 under 35 U.S.C. 156, together with a duplicate of the papers thereof, certified as such.

Please charge Deposit Account No. 16-1445 the amount of $1,120.00. The Commissioner is hereby also asked to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 16-1445. Two duplicates of this paper are enclosed.

Respectfully submitted,

Date: November 18, 1999

Gregg C. Benson
Assistant General Patent Counsel
Reg. No. 30,997
Tel: 860-441-4901

Pfizer Inc.
Patent Department
Eastern Point Road
Groton, CT 06340

PC7068AADO

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE:	**U.S. Patent No. 4,959,366**	:
ISSUED:	**September 25, 1990**	:
TO:	**Peter E. Cross, et al.**	:
FOR:	**Anti-Arrhythmic Agents**	:
FROM:	**Serial No. 44,086**	:
FILED:	**April 29, 1987**	:

Box Patent Extension
Assistant Commissioner for Patents
Washington, D.C. 20231

DECLARATION ACCOMPANYING APPLICATION OF PFIZER INC. FOR EXTENSION OF THE TERM OF U.S. PATENT NO. 4,959,366 UNDER 35 U.S.C. 156

Sir:

I, GREGG C. BENSON, declare as follows:

1. I am a patent attorney. I am a member of the bar of the State of Connecticut and I am authorized to practice before the U.S. Patent and Trademark Office, Registration No. 30,997.

2. I am employed by PFIZER INC., a corporation organized and existing under the laws of the State of Delaware, and having a place of business at 235 East 42nd Street, New York, NY 10017, as Assistant General Patent Counsel. I have general authority from PFIZER INC. to execute and deliver documents and to otherwise act on its behalf in patent matters.

3. PFIZER INC. is the owner of record of United States Patent No. 4,959,366.

4. I have reviewed and I understand the contents of the application of PFIZER INC., dated November 18, 1999, which is being submitted herewith for extension of the term of United States Patent No. 4,959,366 and under 35 U.S.C. §156 and 37 C.F.R. §1.730.

5. I believe that United States Patent No. 4,959,366 is subject to extension pursuant to 37 C.F.R. 1.710.

6. I believe that the length of extension of term of United States Patent No. 4,959,366 of 1827 days which is being claimed by PFIZER INC. is justified under 35 U.S.C §156 and the applicable regulations.

7. I believe that the patent for which extension is being sought meets the condition for extension of the term of a patent as set forth in 35 U.S.C. §156 and 37 C.F.R. §1.720.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statement may jeopardize the validity of the application being submitted herewith or any extension of patent term granted thereon.

Signed this 18th day of November, 1999 at Groton, Connecticut.

Gregg C. Benson
Assistant General Patent Counsel
Reg. No. 30,997
Tel: 860-441-4901

Pfizer Inc.
Patent Department
Eastern Point Road
Groton, CT 06340

slj/7068adec.doc

PC7068AADO

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE:	**U.S. Patent No. 4,959,366**	:
ISSUED:	**September 25, 1990**	:
TO:	**Peter E. Cross, et al.**	:
FOR:	**Anti-Arrhythmic**	:
FROM:	**Serial No. 44,086**	:
FILED:	**April 29, 1987**	:

Box Patent Extension
Assistant Commissioner for Patents
Washington, D.C. 20231

CONSENT OF PFIZER PHARMACEUTICALS
PRODUCTION CORPORATION LIMITED

Sir:

Whereas Pfizer Pharmaceuticals Production Corporation Limited ("PPPCL") is an indirect subsidiary of Pfizer Inc. and a member of the group of companies known as the Pfizer group ("PFIZER"), said Pfizer Inc. being the parent company of PFIZER;

Whereas PPPCL is the owner of New Drug Application ("NDA") No. 20-931 for TIKOSYN (dofetilide), and PPPCL acted as agent for PFIZER in obtaining approval of NDA No. 20-931;

Whereas TIKOSYN (dofetilide) is claimed in Letters Patent of the United States No. 4,959,366, and Pfizer Inc. is the owner of record of said Letters Patent by virtue of an Assignment, recorded in the United States Patent and Trademark Office on the 29th day of April, 1987, at Reel 4780, Frame 0801; and

Whereas PPPCL desires that Pfizer Inc. be able to rely on the marketing approval for TIKOSYN (dofetilide) arising from NDA No. 20-931 in Pfizer Inc.'s application for extension of the term of U.S. Patent No. 4,959,366 under 35 U.S.C. §156;

NOW, THEREFORE, PPPCL hereby confirms that it acted as agent for PFIZER in obtaining the marketing approval for TIKOSYN (dofetilide) arising from NDA No. 20-931; and that it consents and agrees that Pfizer Inc. is fully entitled to rely on said marketing approval for TIKOSYN (dofetilide) arising from NDA No. 20-931 in Pfizer Inc.'s application for extension of the term of U.S. Patent No. 4,959,366 under 35 U.S.C. §156.

Signed and witnessed this 11th day of November, 1999.

PFIZER PHARMACEUTICALS
PRODUCTION CORPORATION
LIMITED

By: _____
Matthew J. Meyer

In the presence of

_____
Mark J. Cooper

Pfizer Inc.
Patent Department
Eastern Point Road
Groton, CT 06340

slj//legal7068acon.doc

PC7068AADO

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE:	**U.S. Patent No. 4,959,366**	:
ISSUED:	**September 25, 1990**	:
TO:	**Peter E. Cross, et al.**	:
FOR:	**Anti-Arrhythmic Agents**	:
FROM:	**Serial No. 44,086**	:
FILED:	**APRIL 29, 1987**	:

BOX PATENT EXTENSION
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Your applicant, Pfizer Inc. ("PFIZER"), a corporation of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York, represents that it is the legal owner of record of Letters Patent of the United States No. 4,959,366, granted to Peter E. Cross, Geoffrey N. Thomas and John E. Arrowsmith[1] on the twenty-fifth day of September, 1990, for Anti-Arrhythmic Agents, by virtue of an assignment, recorded in the United States Patent and Trademark Office on the twenty-ninth day of April, 1987, at Reel 4780, Frame 0801; that Pfizer Pharmaceuticals Production Corporation Limited ("PPPCL") is an indirectly-owned subsidiary of PFIZER; that PFIZER controls, indirectly, all the voting shares of PPPCL; that PPPCL is the owner of New Drug Application ("NDA") No. 20-931 for TIKOSYN (dofetilide), claimed by U.S. Patent No. 4,959,366; and that PFIZER is entitled to rely on the marketing approval for TIKOSYN (dofetilide) arising from NDA No. 20-931.

[1] Subsequently, a certificate of correction (Exhibit 2B) dated May 11, 1999 certified that the correct inventorship is: Peter E. Cross and Geoffrey N. Thomas.

Pursuant to the provisions of 37 C.F.R. 1.730, your applicant hereby applies for an extension of the term of said United States patent of 1827 days under 35 U.S.C. 156, based on the materials set forth herein and in the accompanying papers. In the materials which follow herein, paragraph numbers correspond to the paragraph numbers in 37 C.F.R. 1.740(a).

(1) The approved product is TIKOSYN, which is further identified as follows.

Chemical Name

Methanesulfonamide, N-[4-[2[methyl[2-[4-[(methylsulfonyl)amino]phenoxy]ethyl]amino]ethyl]phenyl]-

also known as

β-[(p-methanesulfonamidophenethyl)methylamino]methanesulfono-p-phenetidide

and also known as

1-(4-methanesulphonamidophenoxy)-2-[N-(4-methanesulphonamidophenethyl)-N-methylamino]ethane

Generic Name

dofetilide

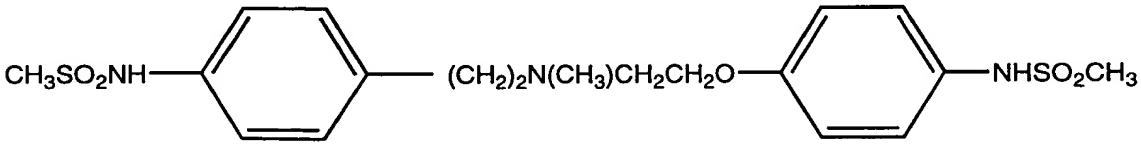
Molecular Formula

$C_{19}H_{27}N_3O_5S_2$

Molecular Weight

441.58

Chemical Formula



(2) TIKOSYN was subject to regulatory review under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(3) TIKOSYN received permission for commercial marketing or use under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) on October 1, 1999.

(4) The active ingredient in TIKOSYN is methanesulfonamide, N-[4-[2[methyl[2-[4-[(methylsulfonyl)amino]phenoxy]ethyl]amino]ethyl]phenyl]- (dofetilide). Said active ingredient has not been previously approved for commercial marketing or use under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act or the Virus-Serum-Toxin Act.

(5) This application is being submitted within the sixty day period permitted for its submission pursuant to 37 C.F.R. 1.720(f). The last day on which this application could be submitted is November 29, 1999.

(6) The patent for which an extension is being sought is identified as follows.

Inventors: Peter E. Cross and Geoffrey N. Thomas

Patent No.: 4,959,366

Title: Anti-Arrhythmic Agents

Issued: September 25, 1990

Expires: September 25, 2007

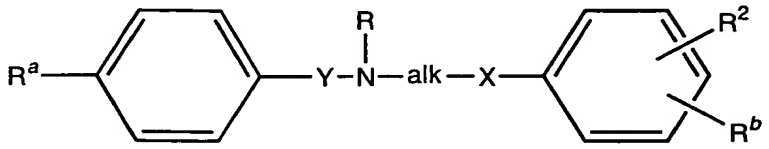
(7) A copy of United States Patent No. 4,959,366, the patent for which an extension is being sought, is attached hereto as EXHIBIT A.

(8) No disclaimer or reexamination certificate has issued for United States Patent No. 4,959,366. A certificate of correction for U.S. Patent No. 4,959,366 was issued on May 11, 1999 (a copy is attached hereto as EXHIBIT B). A copy of the receipt of maintenance fee payment is attached hereto as EXHIBIT C.

(9) United States Patent No. 4,959,366 claims the approved product. Claims 1-46, inclusive, claim the approved product per se. Claim 47 claims pharmaceutical compositions which comprise the approved product. Claim 48 claims methods of treating cardiac arrhythmia by administering the approved product. The manner in which

each applicable patent claim reads on the approved product is as follows:

Claim 1 of U.S. 4,959,366 claims a genus of chemical compounds of the general formula:



or a pharmaceutically acceptable salt thereof;

wherein

R^a is $-NO_2$, $-NH_2$ or $-NHSO_2R^1$ where R^1 is a C_1-C_4 alkyl group;

R^b is $-NO_2$, $-NH_2$ or R^3 where R^3 is $-NHSO_2(-C_1-C_4$ alkyl) or $-CONR^4R^5$ where R^4 and R^5 are each independently H or C_1-C_4 alkyl or together with the nitrogen atom to which they are attached represent a 1-pyrrolidinyl, piperidino, morpholino or N-methylpiperazin-1-yl group; with the proviso that when one of R^a and R^b is $-NO_2$, then the other is not $-NH_2$;

X is O or S absent;

Y is an ethylene group optionally substituted by a methyl group;

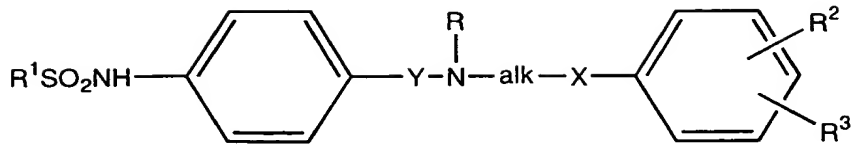
"alk" is an ethylene, trimethylene or tetramethylene group, "alk" being optionally substituted by a methyl group;

R is C_1-C_4 alkyl; and

R^2 is H, halo, CF_3 or C_1-C_4 alkyl.

When the compound of claim 1 is the free base and when R^a is $-NHSO_2R^1$ where R^1 is a C_1-C_4 alkyl group, specifically methyl, R^b is $-NHSO_2(-C_1-C_4)$, specifically $-NHSO_2CH_3$, X is O, Y is an ethylene group, "alk" is an ethylene group, R is C_1-C_4 alkyl, specifically methyl, and R^2 is H, the compound of the formula of claim 1 is dofetilide. Therefore, claim 1 reads on the approved product.

Claim 2 of U.S. 4,959,366 claims a genus of chemical compounds of the general formula:



or a pharmaceutically acceptable salt thereof;
where
R and R^1 are each independently C_1-C_4 alkyl;
X is O or S absent;
Y is an ethylene group optionally substituted by a methyl group;
"alk" is an ethylene, trimethylene and tetramethylene group, "alk" being optionally substituted by a methyl group;
R^2 is H, halo, CF or C_1-C_4 alkyl; and
R^3 is a group of the formula $-NHSO_2(C_1-C_4$ alkyl) or $-CONR^4R^5$ where R^4 and R^5 are each independently H or C_1-C_4 alkyl or together with the nitrogen atom to which they are attached represent a 1-pyrrolidinyl, piperidino, morpholino or N-methylpiperazin-1-yl group.

When the compound of claim 2 is the free base, and when R is C_1-C_4 alkyl, specifically methyl, R^1 is C_1-C_4 alkyl, specifically methyl, X is O, Y is an ethylene group, "alk" is an ethylene group, R^2 is H and R^3 is $-NHSO_2(-C_1-C_4)$, specifically $-NHSO_2CH_3$ the compound of the formula of claim 2 is dofetilide. Therefore, claim 2 reads on the approved product.

Claim 3 of U.S. 4,959,366 claims the compounds of the formula of claim 2 in which the definition of R, X, Y, "alk", R^2 and R^3 are the same as in claim 2, but the definition of R^1 is restricted. In the restricted definition, R^1 is methyl. Thus, claim 3 embraces dofetilide and reads on the approved product.

Claim 4 of U.S. 4,959,366 claims the compounds of the formula of claim 2 in which the definition of R^1, X, Y, "alk", R^2 and R^3 are the same as in claim 2, but the

definition of R is restricted. In the restricted definition, R can be methyl or ethyl. Thus, claim 4 embraces dofetilide and reads on the approved product.

Claim 5 of U.S. 4,959,366 claims the compounds of the formula of claim 3 in which the definition of R^1, X, Y, "alk", R^2 and R^3 are the same as in claim 3, but the definition of R is restricted. In the restricted definition, R can be methyl or ethyl. Thus, claim 5 embraces dofetilide and reads on the approved product.

Claim 6 of U.S. 4,959,366 claims the compounds of the formula of claim 5 in which the definition of R^1, X, Y, "alk", R^2 and R^3 are the same as in claim 5, but the definition of R is restricted. In the restricted definition, R is methyl. Thus, claim 6 embraces dofetilide and reads on the approved product.

Claim 7 of U.S. 4,959,366 claims the compounds of the formula of claim 2 in which the definition of R, R^1, Y, "alk", R^2 and R^3 are the same as in claim 2, but the definition of X is restricted. In the restricted definition, X is O. Thus, claim 7 embraces dofetilide and reads on the approved product.

Claim 8 of U.S. 4,959,366 claims the compounds of the formula of claim 3 in which the definition of R, R^1, Y, "alk", R^2 and R^3 are the same as in claim 3, but the definition of X is restricted. In the restricted definition, X is O. Thus, claim 8 embraces dofetilide and reads on the approved product.

Claim 9 of U.S. 4,959,366 claims the compounds of the formula of claim 4 in which the definition of R, R^1, Y, "alk", R^2 and R^3 are the same as in claim 4, but the definition of X is restricted. In the restricted definition, X is O. Thus, claim 9 embraces dofetilide and reads on the approved product.

Claim 10 of U.S. 4,959,366 claims the compounds of the formula of claim 5 in which the definition of R, R^1, Y,

"alk", R^2 and R^3 are the same as in claim 5, but the definition of X is restricted. In the restricted definition, X is O. Thus, claim 10 embraces dofetilide and reads on the approved product.

Claim 11 of U.S. 4,959,366 claims the compounds of the formula of claim 6 in which the definition of R, R^1, Y, "alk", R^2 and R^3 are the same as in claim 6, but the definition of X is restricted. In the restricted definition, X is O. Thus, claim 11 embraces dofetilide and reads on the approved product.

Claim 12 of U.S. 4,959,366 claims the compounds of the formula of claim 2 in which the definition of R, R^1, X, "alk", R^2 and R^3 are the same as in claim 2, but the definition of Y is restricted. In the restricted definition, Y is $-(CH_2)_2-$. Thus, claim 12 embraces dofetilide and reads on the approved product.

Claim 13 of U.S. 4,959,366 claims the compounds of the formula of claim 3 in which the definition of R, R^1, X, "alk", R^2 and R^3 are the same as in claim 3, but the definition of Y is restricted. In the restricted definition, Y is $-(CH_2)_2-$. Thus, claim 13 embraces dofetilide and reads on the approved product.

Claim 14 of U.S. 4,959,366 claims the compounds of the formula of claim 4 in which the definition of R, R^1, X, "alk", R^2 and R^3 are the same as in claim 4, but the definition of Y is restricted. In the restricted definition, Y is $-(CH_2)_2-$. Thus, claim 14 embraces dofetilide and reads on the approved product.

Claim 15 of U.S. 4,959,366 claims the compounds of the formula of claim 5 in which the definition of R, R^1, X, "alk", R^2 and R^3 are the same as in claim 5, but the definition of Y is restricted. In the restricted definition, Y is $-(CH_2)_2-$. Thus, claim 15 embraces dofetilide and reads on the approved product.

Claim 16 of U.S. 4,959,366 claims the compounds of

the formula of claim 6 in which the definition of R, R^1, X, "alk", R^2 and R^3 are the same as in claim 6, but the definition of Y is restricted. In the restricted definition, Y is $-(CH_2)_2-$. Thus, claim 16 embraces dofetilide and reads on the approved product.

Claim 17 of U.S. 4,959,366 claims the compounds of the formula of claim 7 in which the definition of R, R^1, X, "alk", R^2 and R^3 are the same as in claim 7, but the definition of Y is restricted. In the restricted definition, Y is $-(CH_2)_2-$. Thus, claim 17 embraces dofetilide and reads on the approved product.

Claim 18 of U.S. 4,959,366 claims the compounds of the formula of claim 8 in which the definition of R, R^1, X, "alk", R^2 and R^3 are the same as in claim 8, but the definition of Y is restricted. In the restricted definition, Y is $-(CH_2)_2-$. Thus, claim 18 embraces dofetilide and reads on the approved product.

Claim 19 of U.S. 4,959,366 claims the compounds of the formula of claim 9 in which the definition of R, R^1, X, "alk", R^2 and R^3 are the same as in claim 9, but the definition of Y is restricted. In the restricted definition, Y is $-(CH_2)_2-$. Thus, claim 19 embraces dofetilide and reads on the approved product.

Claim 20 of U.S. 4,959,366 claims the compounds of the formula of claim 10 in which the definition of R, R^1, X, "alk", R^2 and R^3 are the same as in claim 10, but the definition of Y is restricted. In the restricted definition, Y is $-(CH_2)_2-$. Thus, claim 20 embraces dofetilide and reads on the approved product.

Claim 21 of U.S. 4,959,366 claims the compounds of the formula of claim 11 in which the definition of R, R^1, X, "alk", R^2 and R^3 are the same as in claim 11, but the definition of Y is restricted. In the restricted definition, Y is $-(CH_2)_2-$. Thus, claim 21 embraces dofetilide and reads on the approved product.

Claim 22 of U.S. 4,959,366 claims the compounds of the formula of claim 2 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 2, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 22 embraces dofetilide and reads on the approved product.

Claim 23 of U.S. 4,959,366 claims the compounds of the formula of claim 3 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 3, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus claim 23 embraces dofetilide and reads on the approved product.

Claim 24 of U.S. 4,959,366 claims the compounds of the formula of claim 4 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 4, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 24 embraces dofetilide and reads on the approved product.

Claim 25 of U.S. 4,959,366 claims the compounds of the formula of claim 5 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 5, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 25 embraces dofetilide and reads on the approved product.

Claim 26 of U.S. 4,959,366 claims the compounds of the formula of claim 6 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 6, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 26 embraces dofetilide and reads on the approved product.

Claim 27 of U.S. 4,959,366 claims the compounds of the formula of claim 7 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 7, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 27

embraces dofetilide and reads on the approved product.

Claim 28 of U.S. 4,959,366 claims the compounds of the formula of claim 8 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 8, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 28 embraces dofetilide and reads on the approved product.

Claim 29 of U.S. 4,959,366 claims the compounds of the formula of claim 9 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 9, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 29 embraces dofetilide and reads on the approved product.

Claim 30 of U.S. 4,959,366 claims the compounds of the formula of claim 10 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 10, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 30 embraces dofetilide and reads on the approved product.

Claim 31 of U.S. 4,959,366 claims the compounds of the formula of claim 11 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 11, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 31 embraces dofetilide and reads on the approved product.

Claim 32 of U.S. 4,959,366 claims the compounds of the formula of claim 12 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 12, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 32 embraces dofetilide and reads on the approved product.

Claim 33 of U.S. 4,959,366 claims the compounds of the formula of claim 13 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 13, but the definition of R^2 is restricted. In the restricted

definition, R^2 can be H, Cl or CH_3. Thus, claim 33 embraces dofetilide and reads on the approved product.

Claim 34 of U.S. 4,959,366 claims the compounds of the formula of claim 14 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 14, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 34 embraces dofetilide and reads on the approved product.

Claim 35 of U.S. 4,959,366 claims the compounds of the formula of claim 15 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 15, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 35 embraces dofetilide and reads on the approved product.

Claim 36 of U.S. 4,959,366 claims the compounds of the formula of claim 16 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 16, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 36 embraces dofetilide and reads on the approved product.

Claim 37 of U.S. 4,959,366 claims the compounds of the formula of claim 17 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 17, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 37 embraces dofetilide and reads on the approved product.

Claim 38 of U.S. 4,959,366 claims the compounds of the formula of claim 18 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 18, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 38 embraces dofetilide and reads on the approved product.

Claim 39 of U.S. 4,959,366 claims the compounds of the formula of claim 19 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 19, but the

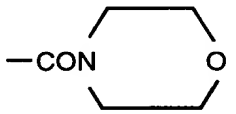
definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 39 embraces dofetilide and reads on the approved product.

Claim 40 of U.S. 4,959,366 claims the compounds of the formula of claim 20 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 20, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 40 embraces dofetilide and reads on the approved product.

Claim 41 of U.S. 4,959,366 claims the compounds of the formula of claim 21 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 21, but the definition of R^2 is restricted. In the restricted definition, R^2 can be H, Cl or CH_3. Thus, claim 41 embraces dofetilide and reads on the approved product.

Claim 42 of U.S. 4,959,366 claims the compounds of the formula of claim 2 in which the definition of R, R^1, X, Y, "alk" and R^3 are the same as in claim 2, but the definition of R^2 is restricted. In the restricted definition, R^2 is H. Thus, claim 42 embraces dofetilide and reads on the approved product.

Claim 43 of U.S. 4,959,366 claims the compounds of the formula of claim 2 in which the definition of R, R^1, X, Y, "alk" and R^2 are the same as in claim 2, but the definition of R^3 is restricted. In the restricted definition, R^3 can be $NHSO_2CH_3$, $-CONH_2$, $CON(C_2H_5)_2$ or

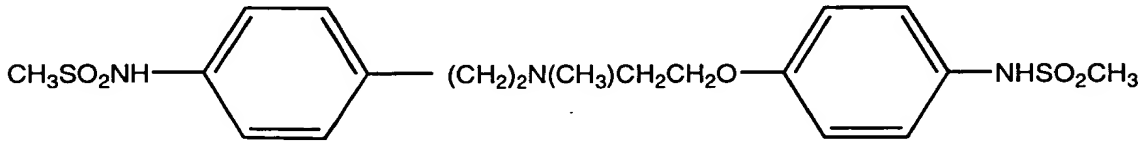


Thus, claim 43 embraces dofetilide and reads on the approved product.

Claim 44 of U.S. 4,959,366 claims the compounds of the formula of claim 43 in which the definition of R, R^1, X, Y, "alk" and R^2 are the same as in claim 43, but the

definition of R^3 is restricted. In the restricted definition, R^3 is $NHSO_2CH_3$. Thus, claim 44 embraces dofetilide and reads on the approved product.

Claim 45 of U.S. 4,959,366 claims a compound of the formula



which is dofetilide per se. Thus claim 45 embraces dofetilide and reads on the approved product.

Claim 46 of U.S. 4,959,366 claims the compounds of the formula of claim 2 in which the definition of R, R^1, "alk", R^2 and R^3 are the same as in claim 2, but the definitions of X and Y are restricted. In the restricted definition, Y is $-(CH_2)_2-$ and X can be O or S. Thus claim 46 embraces dofetilide and reads on the approved product.

Claim 47 of U. S. 4,959,366 claims a pharmaceutical composition comprising an anti-arrhythmic effective amount of a compound of claim 2, or a pharmaceutically acceptable salt thereof, in combination with a pharmaceutically acceptable diluent or carrier. Therefore, claim 47 embraces a pharmaceutical composition containing dofetilide and reads on the approved product.

Claim 48 of U.S. 4,959,366 claims a method of treating cardiac arrhythmia which method comprises administering to an arrhythmic host in need of such treatment an anti-arrhythmic effective dose of a compound of claim 2 in combination with a pharmaceutically acceptable diluent or carrier. Hence, claim 48 embraces the use of dofetilide and reads on the approved product and an approved use of the product.

(10) The relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services to determine the applicable regulatory review period are as follows.

(a) An exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act became effective for dofetilide on August 1, 1990, i.e., 30 days following receipt of Investigational New Drug ("IND") Application No. 35,009.

(b) A New Drug Application ("NDA") under section 505 of the Federal Food, Drug, and Cosmetic Act for TIKOSYN (dofetilide) was initially submitted on March 9, 1998 as NDA 20-931.

(c) NDA 20-931 was approved on October 1, 1999.

(11) A brief description of the significant activities undertaken by or for the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities is attached hereto as EXHIBIT D.

(12) Applicant is of the opinion that United States Patent No. 4,959,366 is eligible for an extension under 35 U.S.C. 156, and the length of extension claimed is 1827 days.

The requirements of 35 U.S.C. 156(a) and (c)(4) have been satisfied as follows.

(a) U.S. Patent No. 4,959,366 claims a product, TIKOSYN (dofetilide, and a method of using the product.

(b) U.S. Patent No. 4,959,366 is currently set to expire on September 25, 2007 (i.e., the term of the patent has not yet expired).

(c) The term of U.S. Patent No. 4,959,366 has never been extended.

(d) This application for extension is being submitted by PFIZER INC., the owner of record of U.S. Patent No. 4,959,366, in accordance with the requirements of paragraphs (1) through (4) of 35 U.S.C. 156(d).

(e) The product, TIKOSYN (dofetilide), has been subject to a regulatory review period under section 505 of the Federal Food, Drug, and Cosmetic Act before its commercial marketing or use, and permission for said commercial marketing or use is the first permitted commercial marketing or use under the Federal Food, Drug, and Cosmetic Act.

(f) No patent has to this date been extended, nor has any other extension been applied for, for the regulatory review period which forms the basis for this application for extension of the term of U.S. Patent No. 4,959,366.

The length of extension of the term of U.S. Patent No. 4,959,366 of 1827 days claimed by applicant was determined according to the provisions of 37 C.F.R. 1.775 as follows.

(a) According to 37 C.F.R. 1.775(b), the length of extension is equal to the regulatory review period for the approved product, reduced as appropriate according to paragraphs (d)(1) through (d)(6) of 37 C.F.R 1.775.

(b) According to 37 C.F.R. 1.775(c), the regulatory review period is the sum of (A) the number of days in the period beginning on the date on which the exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act became effective and ending on the date the NDA was initially submitted under section 505 and (B) the number of days in the period beginning on the date the NDA was initially submitted and ending on the date the NDA was approved. The exemption under subsection 505(i) became effective on August 1, 1990, the NDA was initially submitted on March 9, 1998 and the NDA was approved on October 1, 1999. Hence the regulatory review period is the sum of the periods from August 1, 1990 to March 9, 1998 and from March 10, 1998 to October 1, 1999. This is the sum of 2778 days and 571 days, which is 3349 days.

(c) According to 37 C.F.R. 1.775(d)(1)(i), the number of days in the regulatory review period which were on or before the date on which the patent issued must be subtracted. U.S. Patent No. 4,959,366 issued on September 25, 1990. Hence, the period from August 1, 1990 to September 25, 1990 must be subtracted leaving a reduced regulatory review period of from September 26, 1990 to March 9, 1998 and from March 10, 1998 to October 1, 1999. This is the sum of 2722 days and 571 days which is 3293 days.

(d) 37 C.F.R. 1.775(d)(1)(ii) does not apply.

(e) According to 37 C.F.R. 1.775(d)(1)(iii), the regulatory review period must then be reduced by one-half of the days remaining in the period defined in 37 C.F.R. 1.775(c)(1) after that period is reduced in accordance with paragraphs 37 C.F.R. 1.775(d)(1)(i) and 37 C.F.R.

1.775(d)(1)(ii). This is one-half of 2722 days, which is 1361 days. After subtraction of 1361 days from 3293 days, this leaves a reduced regulatory review period of 1932 days.

(f) When the reduced regulatory review period of 1932 days is added to the expiration date of U.S. Patent No. 4,959,366 (September 25, 2007), this gives a date of January 8, 2013. This latter date is not later than October 1, 2013, the date obtained by adding 14 years to the date of approval of the approved product. Therefore, under paragraphs (d)(2) to (d)(4) of 37 C.F.R. 1.775, applicant is entitled to an extension corresponding to the period from September 25, 2007 to January 8, 2013. This is 1932 days, which is greater than the extension (1827 days) being claimed. Hence, applicant is in compliance with 35 U.S.C. 156(c)(3) and paragraphs (d)(2) to (d)(4) of 37 C.F.R. 1.775.

(g) The five-year limitation of 35 U.S.C. 156(g)(6)(A) and 37 C.F.R. 1.775(d)(5) applies to this application, because U.S. Patent No. 4,959,366 issued after the date of enactment of 35 U.S.C. 156. The date obtained by adding the extension sought (1932 days) to the expiration date of U.S. Patent No. 4,959,366 is January 8, 2013. The latter date is later than September 25, 2012, the date obtained by adding 5 years to the expiration date of U.S. Patent No. 4,959,366. Therefore, under paragraphs (d)(5)(i) and (d)(5)(ii) of 37 C.F.R. 1.775, applicant is entitled to an extension corresponding to the period from September 25, 2007 to September 25, 2012. This is 1827 days, which is the length of extension being claimed. Hence, applicant is in compliance with 35 U.S.C. 156(g)(6)(A) and 37 C.F.R. 1.775(d)(5).

(13) Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and the Secretary of Health and Human Services any information which is

material to the determination of entitlement to the 1827 day extension being sought to the term of United States Patent No. 4,959,366.

(14) The prescribed fee for receiving and acting on this application for extension is to be charged to Deposit Account No. 16-1445, as authorized in the enclosed transmittal letter.

(15) Please address all inquires and correspondence relating to this application for patent term extension to:

Gregg C. Benson
Pfizer Inc.
Patent Department
Eastern Point Road
Groton, CT 06340
860-441-4901

(16) A duplicate of these application papers, certified as such, is enclosed herewith.

(17) A declaration as set forth in 37 C.F.R. 1.740(a)(17) and 1.740(b) is enclosed herewith.

Respectfully submitted,
Pfizer Inc.

Date: November 18, 1999 By: _____

Gregg C. Benson
Assistant General Patent Counsel
Reg. No. 30,997
860-441-4901

Pfizer Inc.
Patent Department
Eastern Point Road
Groton, CT 06340

slj/legal/7068aamn.doc